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**Developing workable research methods: lessons from a pilot study with vulnerable participants and complex assessments**

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Susan Jones is a research associate within the Health and Social Care Institute at Teesside University, UK. She qualified as a Registered Nurse in 1981 then spent four years working in oncology, before leaving to have a family. In 2006 she gained a BSc in Public Health and Well-being (Hons) from Teesside University. In the last three years she has developed her undergraduate dissertation on the role of the school nurse assistant, undertaken a number of literature reviews, worked on several health service evaluations and conducted primary research into taste and smell post-stroke. At present she is working towards a Masters in Health Sciences (Public Health) and her dissertation topic is Stopping Smoking after a Stroke.

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Sharon Hamilton is a Reader in Nursing and Director of the Centre for Health and Social Evaluation at Teesside University in the UK. The majority of her clinical experience was gained in neurosurgical nursing. She has a Masters degree in Social Policy from Goldsmith's, University of London and was awarded a PhD in stroke care and change management from Kingston University. Her research has two main themes: developing the evidence-base underpinning nursing interventions including those in stroke care; and the evaluation of new health services.

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Claire O'Malley is a Research Associate at Durham University. She has a degree in Nutrition and Health Science from the Teesside University and is currently studying for an MSc in Health Science (Public Health Pathway). Claire has been involved in evaluating various obesity and nutrition-related initiatives. Her main research interests lie within the field of childhood obesity and novel ways of measuring dietary intake in both adults and children. Claire is currently working on a project funded through the World Cancer Research Fund (WCRF) entitled TeesCAKE (Tees Consumption and Activity in Kids' Experience) which aims to encourage healthy weight, healthy eating and healthy lives in school children.

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Carol Halton is the Stroke Rehabilitation Lead for South Tees Community Services and was working at James Cook Hospital, Middlesbrough at the time of the study. All her stroke experience has come from within Clinical Practice. Having established a Stroke Rehabilitation Unit within a Community Hospital setting then moved to a large teaching hospital to develop the role of the Stroke Coordinator. She has a degree in General Nursing Studies from York University and undertook degree level modules within Stroke Care.

## **ABSTRACT**

### **Background:**

Following acute stroke, deterioration in nutritional status and weight loss is common; few studies have investigated this, perhaps due to difficulties with recruitment and completion of complex assessments with stroke patients. This study reports the feasibility of a study protocol to determine predictors of nutritional intake in stroke patients.

### **Aim:**

To test the feasibility of a protocol to measure taste and smell function and explore links with dietary intake following stroke.

### **Methods:**

Patients were recruited from one acute stroke unit in 2007/8. Data were collected at three time points and entailed standardised validated assessments of taste and smell function, diet, appetite and mood state.

### **Results:**

Recruitment of this vulnerable population to a demanding assessment schedule was challenging. Of a cohort of 166 admissions, six were recruited and complete data collected from four participants. Slow recruitment was largely due to exacting inclusion criteria and rapid hospital discharge. Those who completed all assessments reported the schedule as tolerable and acceptable.

### **Conclusion:**

This study illustrated the difficulties of recruiting this vulnerable population. Identification of reasons for slow recruitment facilitated development of measures to address them. It was possible to format a complex and lengthy assessment schedule to be acceptable to vulnerable participants.

**200 words**

Key words: recruitment, feasibility, pilot study, taste, smell, stroke, nutrition.

## **INTRODUCTION**

Stroke is one of the top three causes of death and long-term disability in England and internationally; research and service development to improve stroke patient outcomes is a priority (Dept of Health, 2010). However, research recruitment and retention of generally older people with multiple impairments and acute illness, such as stroke patients, is challenging (Schulz et al, 2006). This may be particularly the case where studies require sequential, detailed assessment schedules (Jeffries, 2009). Preliminary stages entailing, for example, theory development and qualitative testing, are an important component of research programme development (Campbell et al, 2000). This paper reports and discusses findings of pilot feasibility work to test a recruitment and assessment protocol prior to initiation of a full-scale study.

### **Nutritional problems in stroke patients**

Nutritional problems are common amongst stroke patients; sequential assessments during acute and rehabilitation stages have demonstrated overall deterioration in nutritional status and weight loss (Davalos et al, 1996; Finestone et al, 1996). This is significant as malnutrition has been associated with increased morbidity and risk of death and dependency after a stroke (Davalos et al, 1996; Gariballa et al, 1998a).

Some patients, particularly older people and stroke patients, do not eat an adequate or balanced diet in hospital (Gariballa et al, 1998a, b). At 30 days post stroke, comparison of food intake of 150 self-feeding stroke patients with their calculated energy and protein requirements revealed nutritional deficits from 60% and 50% of the cohort, respectively (Aquilani et al, 1999). At 5 weeks after a stroke 20 still-hospitalised patients who could swallow normally were eating an average of 1,084 (SD 343) kcal/day: substantially less than requirements (Gariballa et al, 1998b). Whilst nutritional supplements can significantly increase energy and protein intakes, they are seldom used systematically in hospital, and patients do not always consume them in adequate amounts to counteract this deficit. A major international trial indicated routine administration of nutritional supplements to well-nourished stroke patients was not beneficial (FOOD Trial Collaboration, 2005).

Stroke patients experience a variety of disabilities that may deter eating and links between eating disabilities, appetite, mood state and dietary intake have been reported (Perry and McLaren, 2003; 2004). Olfactory (smell) and gustatory (taste) functions both contribute to taste sensation; complaints of altered taste commonly arise from olfactory dysfunction (Getchell et al, 1991). Decreased taste sensation has

been linked with lower body weight and energy intake in older adults and with significant weight loss in stroke patients (De Jong et al, 1999; Finsterer et al, 2004). Taste disturbance has been reported in stroke patients, assessed via a variety of methods. A single small cohort study and a series of case studies have reported deficits in patients with brain lesions at a variety of locations (Heckmann et al, 2005; Pritchard et al, 1999; Onoda et al, 1999). Symptoms ranged from reduced intensity of taste sensation, loss of pleasant associations and conversion of some neutral to noxious tastes, development of smell and taste intolerance, food aversion and marked weight loss. Amongst groups of older adults, taste dysfunction has been linked with reduced appetite and increased susceptibility to infections (Schiffman et al, 2000). Hence smell and taste can be strongly linked with eating, both of quantity and quality of food eaten.

A single research study has systematically investigated taste and smell dysfunction in a group of patients following minor strokes, demonstrating a sizeable proportion, 30%, with poor or lost taste (Heckmann et al, 2005). Case studies and subjective self-report also note loss of and altered taste following stroke (Onoda et al, 1999; Pritchard et al, 1999; Perry and McLaren, 2003). It is hard to estimate from these studies to what degree stroke patients are affected by taste and smell problems, or the extent to which this affects what they eat. No study has explored the potential of such impairments to resolve spontaneously, or attempted to quantify their persistence. These are important gaps in knowledge, bearing in mind the health problems that can result from an inadequate diet.

This is clearly an important area for research, but stroke cohorts present challenges for recruitment and completion of complex assessments (Schulz et al, 2006; Jeffries et al, 2009). Nutritional studies may pose particular hurdles due to the complexity of assessment schedules; a previous nutritional study by this author group recruited 100 of a cohort of 438 stroke patients, and obtained complete datasets for only 38 participants (Nip et al, 2010). Recruitment and data collection have to be tailored to the specific needs of stroke patients, including cognitive and speech impairments, and fatigue. If successfully accomplished, patients with a variety of stroke-related conditions may be able to participate and subsequently produce results clinically relevant across the spectrum of stroke. This study tested the feasibility of a research protocol designed to measure taste and smell function and explore links with dietary intake immediately following stroke.

## **Design and setting**

A cohort study design was used. Participants were recruited from an Acute Stroke Unit (ASU) in one NHS Trust and followed to an inpatient Rehabilitation Unit (RU) in a separate hospital, or home. Ethical approval was obtained from the appropriate committees prior to commencement of the study.

## **Participants**

All patients admitted to one ASU between 09/10/07 – 14/12/07 and 07/01/08 – 18/02/08 were considered for inclusion. Inclusion criteria were:

- $\geq 18$  years of age;
- confirmation of stroke by Computerised Tomography (CT scan);
- sufficient medical stability to sit out of bed and begin therapy.

Exclusion criteria included:

- known gustatory or olfactory impairments,
- significant communication and/ or cognitive impairments, identified through Mini Mental State Examination (MMSE) (Folstein et al, 1975).
- recruitment to another study,
- unable to complete T1 assessment within 14 days of admission,
- unable to complete T2 assessment (e.g. not fully orally fed) within 21 days of assessment.

The latter two exclusion criteria were designed to enable any change within the first month post stroke to be identified at the T3 assessment (at 1 month post-stroke).

## **Data collection**

All consecutively admitted stroke patients were reviewed by the researcher and those meeting the inclusion criteria were approached once medically stable. For consenting patients, the following data were extracted from medical and nursing records, with reliability of data extraction checked independently by a second researcher: age; smoking status; sex; ethnic origin; co-morbidities; current medications (including screening for possible effects on taste); weight; stroke severity assessed at admission using the National Institute of Health Stroke Severity scale (Goldstein and Samsa, 1997); the Oxfordshire stroke sub-type (Bamford et al, 1990); CT scan findings.



## Measurement battery

Measurements were conducted once participants were medically stable (T1); when a normal, oral diet was established (T2); at one month post stroke (T3). Assessments were performed in a quiet area, away from strong smells. The following standardised, validated assessments were undertaken by study participants:

- Olfactory function tested using 'Sniffin' Sticks', a proprietary test kit using a well-established, standard procedure used extensively in studies of older adults and in clinical work (Hummel et al, 1997; Schiffman et al, 2000). This test was first produced in 1996 and has since been widely used and validated (Kobal et al, 2000). Testing entails a forced choice procedure comprising threshold, discrimination, and identification (TDI) testing. Odour identification is accomplished with 16 pens filled with standard odorants (e.g. rose, lemon, garlic, leather) presented with multiple choice response options. Threshold and discrimination testing is accomplished using similar pens filled with differing concentrations of n-butanol, again with forced choice response options, in stepwise concentrations. A mean composite TDI score was calculated.
- Gustatory function tests including taste threshold and identification was assessed using "Taste Strips". This involved 16 Taste Strips and 2 blanks, representing the 4 major tastes in a range of concentrations, being placed on the tongue one after the other in a pseudo-randomised sequence for identification and to establish threshold values. This has been shown to be a valid and reliable test procedure (Mueller et al, 2003), posing minimal hazard for those whose swallow function is not safe with thin fluids (Garon et al, 1997).
- Oral health and hygiene was evaluated using the THROAT assessment tool. This ordinal, nine item scale assesses the condition of the mouth on a scale of 0 – 3, and has demonstrated both inter and intra-rater reliability (Dickinson et al, 2001).
- The Eating Disabilities Assessment Scale (EDAS) was used. This ordinal scale covers eight types of disabilities that impact on ability to eat, assessed by observation. Internal consistency and inter rater reliability were initially judged as acceptable (McLaren and Dickerson, 2000).
- Patients' height in m<sup>2</sup> and weight in kg were used to calculate Body Mass Index and triceps skinfold thickness used as a measure of subcutaneous fat (Gibson 1993).
- The Mini Nutritional Assessment (MNA) (Guigoz et al, 1994) was completed; this widely validated composite nutritional assessment scale has been used extensively in international studies. Originally developed with older adults, it has been

validated and demonstrated good reliability when used by different healthcare professionals (Guigoz et al, 1994)

- The Hospital Anxiety and Depression Scale (HADS) (Zigmond and Snaith, 1983) was used. Widely used with a broad range of patient groups, it has demonstrated concurrent validity with stroke patients (O'Rourke et al, 1998).
- The Appetite, Hunger and Sensory Perception questionnaire (AHSP) (Mathey et al, 2001) is a measure of self-reported appetite, taste and smell, developed for and repeatedly used with elderly participants, and in a South London stroke study (Nip et al, 2010).

Dietary intake was measured via standard weighed food procedures (Gibson, 1993) during a single 24 hour period, following establishment of full oral intake. The researcher was present on the ward during breakfast, lunch and dinner. Weighed food data collection methods were negotiated at the study site, to tailor them to the procedures of the two hospitals. Where food was plated on the ward, it was weighed immediately prior to presentation to the patient. Where plated in the kitchen, food was weighed by kitchen staff, prior to heating.

At T1 and T3 the THROAT, gustatory and olfactory assessments only were completed, with all measures being undertaken at T2. At T2 dietary intake and anthropometric data were collected, and the MNA, EDAS, HADS and AHSP questionnaires were completed by the researcher during face to face interviews with participants. The interview was formatted such that the order of questionnaire delivery was structured to progress from simple questions working up to more complex ones. A single question at conclusion of each completed set of assessments sought acceptability of the schedule to participants.

### **Field Diary**

The researcher maintained a free-hand record of all process issues that arose during data collection, notably around recruitment and assessment, in order to identify factors impacting upon protocol delivery.

### **Analysis**

Records were maintained of all activities, and notes made of details affecting protocol delivery. Assessment data were entered using SPSS for Windows Version 13; findings reported in this paper solely address study aims of feasibility testing of the recruitment and assessment protocol.

## **FINDINGS**

### **Recruitment and T1 assessment**

Initial efforts were focused on establishing processes to enable data collection without hindering hospital or clinical procedures. This was most challenging for the weighed food intake data, with the two hospitals employing differing catering systems.

Satisfactory processes were established following extensive negotiation with all relevant staff groups.

During the 11 week study period, 166 patients were admitted with a clinical diagnosis of stroke, of whom six were eligible for recruitment (Figure 1). The most common reason for excluding patients was that acute stroke was not identified by CT scan (n=67). Of these patients, thirty-three were potentially eligible for recruitment: fifteen would have been eligible if inclusion criteria had relied on clinical diagnosis alone; eighteen remained unconfirmed clinically or by scan.

Thirty patients were discharged too rapidly for recruitment. The mean duration from admission to recruitment for the 6 recruits was 4 days, range 1 – 7 days; mean length of stay in the ASU was 7, range 6-11, days. For the group whose initial CT did not confirm stroke, mean ASU length of stay was 6 days.

Other reasons for exclusion were: poor communication (n=20); acutely unwell/medically unstable (n=18); cognitive impairment (n=8); requiring surgery (n=2); participating in another study (n=4); pre-existing gustatory impairment (n=3); cognitive impairment (n=3); consent withheld (n=2); risk of violence to researcher (n=1); unable to complete T1 within 14 days of admission (n=1); unable to complete T2 as remained nil orally (n=1).

Of the patients who were judged too unwell to recruit on admission, nine were monitored weekly but continued too drowsy or confused. Eight continued to show significant cognitive impairment and one showed promise of recovery but still was unable to complete the first assessment by day 14 following admission.

All six patients meeting the inclusion criteria completed T1 assessments.

### **T2 and T3 assessments**

Of these six participants, five completed T2 assessments and the 24 hour food record; one was transferred then discharged home prior to food intake assessments,

and subsequently withdrew from the study. One participant moved out of area after completing T2. Four participants completed T3 and therefore all assessments (T1, T2 and T3).

### **Acceptability for participants**

Participants reported the assessments at T1 and T2 as acceptable and tolerable; one participant reported the experience at T3 as wearisome, and another withdrew once at home. Initial consent was withheld for two potential participants; one patient and one relative (in discussion with the patient) felt the study would be too onerous. To ameliorate the demands of the study patients were offered breaks during the assessment process; however neither this offer nor the option to discontinue due to weariness were taken up by any participant. Some participants initially appeared more motivated than others; some appeared to sustain motivation over time more readily. All expressed interest in the taste and smell tests, appeared to enjoy them and wanted to know their results immediately. Other tests appeared of less interest to participants.

## **DISCUSSION**

The aim of the study was to test the feasibility of a protocol to measure taste and smell function and links with dietary intake after stroke, in terms of recruitment and completion of assessments.

### **Recruitment**

Numbers recruited were substantially less than had been anticipated from previous admission data; a number of issues affected recruitment.

A key finding was that the speed at which patients progressed through the ASU militated against recruitment, also noted by Jeffries et al (2009). As speed in recognising, admitting and rehabilitating patients is a key factor in improving outcomes (Department of Health, 2010) researchers need to find ways of working within this framework, especially given the steady decrease in mean length of stay demonstrated by the National Sentinel Audit for Stroke. For example, from 2001 to 2008 total hospital length of stay including rehabilitation reduced from 34 to 23.7 days (Hoffman et al, 2002, 2009). However, this represents an aggregate of all those who are admitted and discharged from an ASU, including those with minor stroke symptoms, those deemed likely to benefit from rehabilitation which may require transfer to another location, and those who are severely affected and may or may not recover sufficiently for active rehabilitation. Stroke audits do not collect data

separately for each component of care, given that patients may receive acute and rehabilitation services on any combination of a general ward, ASU, Combined or Comprehensive Unit, and a RU which may be on the same or different site to the acute service. Recruitment for most studies tends to focus on the 'middle band' stroke group (neither those most nor least severely affected) but detail of their specific treatment patterns may not be available. As in this study, it may be difficult to anticipate parameters of clinical management within which research activities must be accommodated.

Some patients were not well enough to be recruited in the early days after admission; Jeffries et al (2009) also found ill health and fatigue limited recruitment. Although these patients were monitored by the research assistant to see if swallowing, confusion and/or communication skills would improve sufficiently to meet eligibility criteria, most often, if they recovered sufficiently to meet recruitment criteria, this occurred some considerable time after admission and they were transferred for rehabilitation before informed consent could be obtained. Whilst participants were followed from one site to another, early transfer to off-site facilities for rehabilitation posed a hurdle for recruitment. This should be born in mind at project set-up, and, if time-post-stroke is not critical for assessment data, methods to offer delayed recruitment established.

For many studies patients' specific patterns of impairment limit recruitment; Jeffries et al (2009) reported less than 1 in 3, Nip et al (2010) less than 1 in 4 stroke patients met study inclusion criteria. In this study, presenting characteristics of 34 stroke patients barred their recruitment. More often, however, uncertainties around diagnosis and the severity of their condition were the barrier. Such patients are difficult, often impossible to recruit, yet any service development arising from the research should not ignore them. The mean stroke severity score of the cohort recruited by Heckman et al (2005) indicated most participants experienced mild to moderate levels of impairment. This study suggests these patients may be the group most suitable to participate with this sort of protocol. Whilst it may be feasible to complete a simplified form of the protocol with those with cognitive and/or communication deficits (Perry, 2004), timely recruitment may still pose challenges. Further work will be required to establish and pilot a simplified protocol suitable for completion by those with mild impairments.

Diagnosis via CT scan as an inclusion criterion proved a limiting factor to recruitment. Early CT scans are used primarily to exclude haemorrhage rather than diagnose stroke, and thrombo-embolic lesions are often not visible early on. In hindsight, some patients were excluded unnecessarily. The merits of clinical diagnosis of stroke have been debated as the validity of the resultant diagnosis can be variable (Liu et al, 1999). However, studies examining the reliability and validity of clinical classification of stroke suggest that clinical diagnosis may have an acceptable level of accuracy for recruitment to many studies (Smith et al, 2001; Parsons et al, 2009). Thus use of this rather than CT scan as an inclusion criterion may facilitate recruitment.

Finally, this pilot study was not adopted by the relevant Stroke Local Research Network (LRN) and recruitment was therefore not supported by Network resources. Adoption by an LRN has been demonstrated to increase recruitment (Picker, 2008) and is therefore recommended for future studies.

### **Feasibility of assessments**

In relation to completion of assessments, timing was found to be problematic. The 24-hour food record required completion in hospital at T2; however, many patients were discharged home as soon as full oral diet was established. A period of time needed to elapse between T1 and T2 to allow measurement of change but some who met the inclusion criteria achieved T2 criteria at recruitment, resulting in a single assessment point simultaneously for T1 and T2. With hindsight, in this study T1 and T2 could have been a single assessment point.

Those patients who were recruited reported that the rather lengthy assessment schedule was nonetheless acceptable and achievable. This was probably helped by the deliberate structuring of multiple items from different questionnaires into a logical conversational flow. This demonstrated that, whilst there were recruitment hurdles to be overcome, the assessment schedule of the study was feasible with this population group.

### **CONCLUSION**

Stroke is a disease with high morbidity and mortality rates; development of therapies to maximise recovery is essential. Research to support service development may require complex assessments to be undertaken with this vulnerable group of participants. This study demonstrated the challenges of recruiting such participants, identified potential strategies to maximise recruitment, and the feasibility of the

assessment schedule with those participants who could be recruited, although further work will be required to develop a simplified protocol suitable for completion by those with mild cognitive impairment. Findings have supported development of a full-scale proposal and may be encouraging to other stroke researchers.

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Conflict of Interest: None.

#### Key points

- Information provided by this pilot feasibility study identified elements of the protocol that restricted recruitment and posed barriers to collection of full datasets.
- Information provided by this pilot feasibility study indicated revision of eligibility criteria to clinically rather than CT confirmed diagnosis of stroke to maximise recruitment.
- Information provided by this pilot feasibility study indicated reduction of the number and timing of assessment time-points to maximise collection of full datasets.
- Information provided by this pilot feasibility study flagged the challenges of reducing length of stay for recruitment, and the need to develop strategies to maximise recruitment within restricted time frames.
- Conduct of this pilot study enabled fine-tuning of the protocol for full-scale study to improve effective and timely research project delivery; lessons of this pilot may be useful for other researchers in similar fields.

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**Figure 1: Recruitment Flowchart** (Moher et al, 2001)

